

### REMARKS

Claims 52-55 are pending and were subjected to examination in the final Office Action dated January 11, 2006. Claims 52-55 stand rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,223,285 (DeMichele et al.) in view of EP 0 782 827 (Igarashi et al.) and U.S. Patent No. 4,154,863 (Kahn et al.). Applicants respectfully traverse this rejection below.

The Office Action states that the rejection is maintained for the reasons stated in the previous Office Action, dated June 1, 2005. Office Action, page 2. The Office Action further states that the claims of the present invention are drawn to the same technical formulation of nutritional and dietary supplement (as that of Blend C in Table 2 (col. 9, lines 32-65) of DeMichele et al.). The Office Action then concludes that the "amounts of active agents to be used are deemed obvious since they are all within the knowledge of the skilled pharmacologist" and "once the usefulness of a compound is known to be useful in nutritional supplement, it is within the skill of the artisan to determine the optimum ratio." Office Action, page 3.

The present rejection is based on both a factual misunderstanding of the cited references and a legally erroneous standard of obviousness.

#### **Legal Standard for Obviousness.**

The outstanding rejection amounts to an argument that the combination of known ingredients cannot result in a patentable food or nutritional product. This position is clearly not supported by the law. Further, the MPEP states that "claims should not be rejected on the ground of old combination." MPEP § 2173.05(j). In fact, the patentability of combinations of known elements is of ancient authority. *In re Wright*, 6 U.S.P.Q. 1959, 1962 (Fed. Cir. 1988).

Instead, the proper focus of an obviousness inquiry is the "invention as a whole". *Stratoflex, Inc. v Aeroquip Corp.*, 218 U.S.P.Q. 871 (Fed. Cir. 1983); see also MPEP § 2141.02(I). The Court of Appeals for the Federal circuit has stated that "[a] traditional problem with focusing on a patent as 'a combination of old elements' is the attendant notion that patentability is undeserving without

some 'synergistic' or 'different' effect." *Custom Accessories v. Jeffrey-Allan Industries*, 1 U.S.P.Q. 1196, 1198 (Fed. Cir. 1986).

In the present application, the Office Action is failing to focus on the "invention as a whole". Instead, the Office Action focuses on the invention as a combination of known elements and requires a surprising and unexpected result be shown in order to be patentable over the cited prior art. This is an incorrect focus of an obviousness inquiry.

In order to establish a *prima facie* case of obviousness, the Patent Office must satisfy three requirements. First, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. See *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). Second, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some teaching or suggestion that would have motivated the skilled artisan to modify a reference or to combine references. *Iron Grip Barbell Co., Inc., v. USA Sports, Inc.*, 392 F.3d 1317, 1320 (Fed. Cir. 2004), (see also *In re Fine*, 837 F.2d 1071, 1075 (Fed.Cir.1988) (teachings of a reference can be combined only if there is some suggestion or incentive to do so) (emphasis in the original). The third requirement is that the proposed modification or combination of the prior art must have a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir. 1991); see also *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

In the present application, a *prima facie* case of obviousness has not been established because the cited references fail to teach or suggest all the claim recitations of the present invention, and further, they fail to provide a teaching or suggestion to combine or modify the references so as to enable the skilled artisan to arrive at the claimed invention.

**Obviousness Rejection.**

The cited references, DeMichele et al., Kahn et al., and Igarishi et al., alone or in any combination, fail to disclose all of the elements of the presently claimed invention. Furthermore, one of ordinary skill in the art would have had no reason to modify the composition of DeMichele et al. to arrive at the presently claimed dietary supplement based on DeMichele et al. alone or in combination with Kahn et al. and Igarashi et al.

The Office Action dated June 1, 2005 (presenting the arguments upon which the outstanding obviousness rejection is maintained) argues that Table 2 of DeMichele et al. discloses a nutritional composition containing 40 weight percent of fish oil and borage oil. This Office Action alleges that the sum of the oils in DeMichele et al. read on the instantly claimed 35% of oils in claim 52.

This is an incorrect reading of DeMichele et al.

As Applicants previously pointed out (response dated October 3, 2005), Table 2 shows the composition of **only the lipid blend** in the PULMOCARE® based diet. Thus, this table shows that **borage oil and fish oil make up 40% by weight of the lipid blend alone and not 40% by weight of the total nutritional composition of DeMichele.** Table 7 of DeMichele makes this fact even more apparent as it describes the entire product composition of which the lipid Blend C is a component (See Table 7 and column 15, lines 45-48). As shown in Table 7, fish oil and borage oil account for 4.36 grams each in a total composition of 8 ounces (227grams). Thus, **fish and borage oil together account for less than 4% by weight of the total nutritional composition as taught by DeMichele et al.** ( $4.36 + 4.36 = 8.7 \text{ g}$ ;  $8.7 \text{ g} / 227 \text{ g} = 3.83\%$ ). In contrast, the present invention teaches a composition wherein the borage oil and fish oil comprise 35% of the total composition. Thus, the sum of the oils (fish oil and borage oil) taught in DeMichele et al. of 3.83% cannot be said to read on the 35% weight percent recited in claim 52 of the present invention.

Further, as pointed out in a previous response (dated October 3, 2005), the diet of DeMichele et al. has a **low carbohydrate** content. The low carbohydrate content is designed to reduce carbon dioxide production so as to

minimize the carbon dioxide retention characteristic of pulmonary disease (see, e.g., col. 9, lines 34-38). The nutritional composition in Table 7 of DeMichele et al. (containing the oil Blend C from Table 2; see column 15, lines 45-48) contains 10.28 weight percent carbohydrate. In contrast, the claims of the present invention recite "**25 weight percent sucrose.**" One of ordinary skill in the art would not have had any motivation to formulate a dietary supplement comprising 25% weight percent sucrose based on the teachings of a **low carbohydrate diet** for treating pulmonary disease found in DeMichele et al.

The MPEP states "[i]f a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (see MPEP§2143.01(V)). Clearly, DeMichele et al., modified as suggested in the Office Action, would be rendered unsatisfactory for its intended purpose of providing a low carbohydrate diet for the treatment of pulmonary disease. Therefore, no suggestion or motivation can be found to make the modification of DeMichele et al. as is proposed in the Office Action in order to arrive at the composition of the present invention.

Finally, Applicants respectfully disagree with the contention in the Office Action dated January 11, 2006, that the amounts of active agents are deemed obvious because it is within the skill of the artisan to determine the optimum ratio. Office Action, page 3. As an initial point, the composition recited in the pending claims is used for a different purpose than that of DeMichele et al.; to treat patients with inflammatory disorders as compared to treating pulmonary patients as recited in DeMichele et al. Thus, one of ordinary skill would not be motivated to modify the claimed compositions to treat inflammatory disorders. Furthermore, simple "optimization" of the amounts of active agents described in DeMichele et al. would not result in the compositions recited in the present claims because the claimed compositions and those of DeMichele et al. are dramatically different. For example, the pending claims recite 35% EPA and GLA as compared with 3.8% for DeMichele et al., and 25% carbohydrate in the present claims as compared with 10.28% for DeMichele et al. Clearly, simple

optimization of DeMichele et al. using routine experimentation would not allow one of skill in the art to arrive at the composition as recited in the pending claims.


In sum, DeMichele et al. fails to teach or suggest all of the limitations of the presently claimed invention, and further it fails to provide a teaching or suggestion that would have motivated the skilled artisan to modify the composition of DeMichele et al. to arrive at the present invention. Furthermore, the deficiencies of the DeMichele et al. reference cannot be remedied by combination with Igarashi et al. and Kahn et al. which also fail to disclose or suggest the presently claimed dietary supplement. Accordingly, claims 52-55 of the present invention are non-obvious over DeMichele et al., alone or in combination with Igarashi et al. and Kahn et al.

In view of the foregoing, Applicants respectfully submit that the dietary supplement recited by claims 52-55 is not obvious in view of DeMichele et al. in combination with Igarashi et al. and Kahn et al., and respectfully request that the outstanding rejection on this basis be withdrawn.

**Conclusion.**

The concerns of the Examiner having been addressed in full, Applicants respectfully request withdrawal of outstanding rejection and the issuance of a Notice of Allowance forthwith. The Examiner is encouraged to address any questions regarding the foregoing to the undersigned attorney, who may be reached at (919) 854-1400.

Respectfully submitted,

  
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